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EXAMINER	
CROW, ROBERT THOMAS	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/790,063	KOHARA ET AL.	
	Examiner	Art Unit	
	Robert T. Crow	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,19,21 and 23-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,19,21 and 23-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 August 2008 has been entered.

Status of the Claims

2. This action is in response to papers filed 12 August 2008 in which claim 1 was amended, no claims were canceled, and new claims 23-34 were added. All of the amendments have been thoroughly reviewed and entered.

The interview summary is acknowledged and the interview record is complete.

The objections to the drawings listed in the previous Office Action are maintained and are reiterated below.

The previous rejections under 35 U.S.C. 112, first paragraph, are withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

Claims 1-9, 19, 21, and 23-34 are under prosecution.

Claim Interpretation - 35 USC § 112, Sixth Paragraph

3. The following is a quotation of the sixth paragraph of 35 U.S.C. 112:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

4. Applicant has invoked 35 USC § 112 Sixth Paragraph in the limitation "solution flow introducing means for introducing a solution flow into the vessel" in lines 10-11 of independent claim 1. While the limitation meets the three-prong analysis for consideration under 35 USC § 112 Sixth Paragraph, the limitation is not being treated under 35 USC 112, sixth paragraph because the specification does not provide a limiting definition of the structural elements that define the structure of the means that provides the various functions found in the claims. Thus, the claims are given the broadest reasonable interpretation consistent with the specification (*In re Hyatt*, 211 F.3d1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000) (see MPEP 2111 [R-1]).

Specification/Drawings

5. The drawings were received on 18 December 2007. As noted in the previous Office Action, these drawings are not acceptable.

As noted in the previous Office Action, the amended drawings filed 18 December 2007 are objected to under 35 U.S.C. 132(a) because they introduce new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter

into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: amended Figures 4A-4G each include a “Solution Flow Controlling Unit” and a “Magnetic Member Controlling Unit.” A review of the specification yields a recitation of “an introducing means for introducing a sample and solution into the vessel” and “a position-control means disposed outside of the vessel for magnetically controlling a relative position of the magnetic micro-particles" on page 3. Page 8 also recites an embodiment wherein the "the magnets can be moved in two or three dimensional directions by a magnets [sic] moving mechanism for controlling a position of the magnets.” However, the specification contains no recitations of a “controlling unit” of any kind, nor does the specification recite control of the flow of solutions. Thus, recitation of a “Solution Flow Controlling Unit” in the amended drawings constitutes new matter. In addition, the recitation of a “Magnetic Member Controlling Unit” encompasses embodiments other than the “position-control means” on page 8 of the specification, and therefore constitutes new matter.

6. Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Arguments

Applicant's arguments filed 12 August 2008 (i.e., the “Remarks”) have been fully considered but they are not persuasive for the reason(s) below.

Applicant argues on pages 10-11 of the Remarks that the objection to the drawings and the rejection of claims 1-9, 19, and 21 under 35 USC First Paragraph are

overcome by removal of the language respecting a solution flow controlling unit and a magnetic member controlling unit.

However, Applicant has only removed the language from the claims, and has not removed said language from the drawings. Thus, while the rejection of claims 1-9, 19, and 21 under 35 USC First Paragraph is withdrawn in view of the amendments to the claims, the objection to the drawings is maintained because the new matter is still present in the drawings.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 21, and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Forrest et al (U.S. Patent No. 4,141,687, issued 27 February 1979).

Regarding claim 1, Forrest et al teach a system. In a single exemplary embodiment, Forrest et al teach a system comprising a conduit 56, which is a vessel, wherein magnetic particles are held therein and which receives a sample (Figure 3a, Abstract, and column 9, lines 10-67). A plurality of magnetic traps (i.e., members) 60 and 62 disposed outside the vessel (Figure 3a and column 9, lines 10-67). The magnets are electromagnets (column 3, lines 35-45), which are operated in a particular timed sequence by a controller in the form of programmer 64 (Figure 1 and column 9,

lines 10-67). The programmer independently sends signals to each of the magnetic members because the first magnetic tap is energized separately from the second magnetic trap (column 9, lines 34-65), and each of the magnetic members therefore are arranged to be set off by a corresponding one of the independently received signals and are downstream from the solution flow (Figures 3A-3C). The system of Forrest et al further comprises a solution flow introducing means in the form of a pump (column 6, lines 55-67).

It is noted that the courts have held that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In addition, "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch &Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Therefore, the various uses recited in claim 1 (e.g., setting the magnets on or off in order of location from downstream of the solution flow) fails to define additional structural elements of the claimed device. Because the Forrest et al teaches the structural elements of the claim, the claim is anticipated by Forrest et al. See MPEP § 2114.

Regarding claim 21, Forrest et al teach the system of claim 1, further comprising a collecting vessel collecting one of the magnetic microparticles; namely, a receiver to collect to solid phase (i.e., magnetic microparticles; column 3, line 63-column 4, line 15).

As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claim 21 (e.g., moving the particle that is collected) fails to define additional structural elements of the claimed system. Because the Forrest et al teaches the structural elements of the claim, the claim is anticipated by Forrest et al.

Regarding claims 23 and 26, the system of claim 1 is discussed above. As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claim 23 (e.g., collecting magnetic microparticles one-by-one from an opening end of the vessel by on/off switching of the magnetic fields) and in claim 26 (e.g., collecting an individual one of the magnetic microparticles from the vessel by the on-off switching of the magnetic fields) fails to define additional structural elements of the claimed system. Because the Forrest et al teaches the structural elements of the claims, the claims are anticipated by Forrest et al.

Regarding claim 24, the system of claim 1 is discussed above. Forrest et al also teach the solution flow introducing means is arranged to introduce the solution into the vessel so as to convey the magnetic particles from the opening end of the vessel; namely, the pump (i.e., solution flow introducing means) controls flow of the particles into the vessel (column 6, line 55-column 7, line 50).

As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claim 24 (e.g., conveying the magnetic microparticles one-by-one from an opening end of the vessel by on/off switching of the magnetic fields) fails to define additional structural elements of the claimed system.

Because the Forrest et al teaches the structural elements of the claim, the claim is anticipated by Forrest et al.

Regarding claim 25, the system of claim 1 is discussed above. Forrest et al further teach the system comprises a washing solution vessel in the form of wash receptacle 18, which is connected to pump tube 12 (Figure 1 and column 6, line 55-column 7, line 50), and thus is connected to the pump (i.e., solution flow introducing means).

As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claim 25 (e.g., introducing the washing fluid into the vessel before the magnetic members are set on) fails to define additional structural elements of the claimed system. Because the Forrest et al teaches the structural elements of the claim, the claim is anticipated by Forrest et al.

Response to Arguments

A. Applicant argues on page 11 of the Remarks that Forrest does not teach independent control of the magnets.

However, as noted above, magnetic members (i.e., electromagnets; column 3, lines 35-45) are operated in a particular timed sequence by a controller in the form of programmer 64 (Figure 1 and column 9, lines 10-67). The programmer independently sends signals to each of the magnetic members because the first magnetic tap is energized separately from the second magnetic trap (column 9, lines 34-65), and each of the magnetic members therefore are arranged to be set off by a corresponding one of

the independently received signals and are downstream from the solution flow (Figures 3A-3C).

B. Applicant further argues on page 11 of the Remarks that Forrest et al do not teach controlling the state of magnets from downstream of a solution flow.

However, as noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claim 1 (e.g., setting the magnets on or off in order of location from downstream of the solution flow) fails to define additional structural elements of the claimed device. Because the Forrest et al teaches the structural elements of the claim, the claim is anticipated by Forrest et al.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 19, 2-4, 6-8, 21, and 23-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd Mehta et al (PCT International Application Publication No WO 00/50172, published 31 August 2000) in view of Forrest et al (U.S. Patent No. 4,141,687, issued 27 February 1979).

Regarding claim 1, Burd Mehta et al teach a microparticle array analyzing system. In a single exemplary embodiment, Burd Mehta et al teach a vessel in the form of channel region 415 of a microfluidic device of Figure 3A (page 22, line 29-page 24, line 33). Burd Mehta et al also teach a capillary sips a sample form a microtiter plate and delivers the sample to the channel (page 16, lines 8-10); thus, the vessel is arranged to receive the sample. Burd Mehta et al teach a first magnetic particle set, which is a plurality of magnetic microparticles, creates a particle retention region for a second set (i.e., plurality) of non-magnetic particles in the channel (page 31, lines 7-19).

Burd Mehta et al further teach a plurality of magnet members disposed outside of the channel for magnetically controlling a relative position of the magnetic microparticles with respect to the vessel; namely, the microfluidic device incorporates a combination of magnetic control elements for modulating a magnetic field within the channel (page 16, lines 1-10). The combination of magnetic control elements is interpreted as a plurality of magnetic control elements. Burd Mehta et al further teach the magnetic members create a magnetic field proximal to the channel for magnetically controlling the position

of the magnetic particles with respect to the vessel (page 22, line 29-page 23 line 10). Because Burd Mehta et al teach the magnetic field that is proximal to the channel is an alternative embodiment to a magnetic field within the particle retention region in the channel (page 23, lines 7-10), the magnetic control elements are interpreted as being outside the vessel.

Burd Mehta et al further teach a solution flow introducing means for introducing a solution flow in the vessel; namely, electrokinetic controllers in combination with pressure based flow for regulating fluid flow (page 17, line 30-page 18, line 10) in combination with the magnetic elements (page 16, lines 1-10).

Burd Mehta that teach the magnets create an electromagnetic field (page 20, lines 1-10), that the magnetic field controls magnetically controlling the position of the magnetic particles with respect to the vessel (page 22, line 29-page 23 line 10), that the particle flow is controlled (page 91, lines 1-10), and that the system comprises a controller in the form of a computer for controlling the instrumentation of the system (page 89, lines 25-34). However, Burd Mehta et al do not explicitly teach the controller independently signals each of the electromagnets to independently turn on and off.

However, Forrest et al teach a system in the form of conduit 56, which is a vessel, having a plurality of magnetic traps (i.e., members) 60 and 62 disposed outside the vessel (Figure 3a and column 9, lines 10-67). The magnets are electromagnets (column 3, lines 35-45), which are operated in a particular timed sequence by a controller in the form of programmer 64 (Figure 1 and column 9, lines 10-67). The programmer independently sends signals to each of the magnetic members because

the first magnetic tap is energized separately from the second magnetic trap (column 9, lines 34-65), and each of the magnetic members therefore are arranged to be set off by a corresponding one of the independently received signals and are downstream from the solution flow (Figures 3A-3C). Forrest et al also teach the system has the added advantage of allowing the process of using the system to be automated while providing an efficient compact unit (column 6, lines 40-45). Thus, Forrest et al teach the known technique of having a controller that independently signals each of the electromagnets to independently turn on and off.

As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claim 1 (e.g., setting the magnets on or off in order of location from downstream of the solution flow) fails to define additional structural elements of the claimed device. Because the prior art teaches the structural elements of the claim, the claim is obvious over the prior art.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the system comprising a plurality of magnets producing an electromagnetic field with a controller as taught by Burd Mehta et al so that the controller independently signals each of the electromagnets to independently turn on and off as taught by Forrest et al to arrive at the instantly claimed system with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a system having the added advantage of allowing the process of using the system to be automated while providing an efficient compact unit as explicitly taught by Forest et

al (column 6, lines 40-45). In addition, it would have been obvious to the ordinary artisan that the known technique of using the controller that individually switches the field of a plurality of electromagnets on and off as taught by Forrest et al could have been applied to the system of Burd Mehta et al with predictable results because the controller that individually switches the field of a plurality of electromagnets on and off as taught by Forrest et al predictably results in a system useful in biomolecular assays.

Regarding claim 19, the system of claim 1 is discussed above. Burd Mehta et al teach the system further comprises a plurality of non-magnetic particles held by the vessel, wherein the magnetic microparticles and the non-magnetic particles are arranged in a sequence within the vessel; namely, the plurality of magnetic microparticles creates a particle retention region for a second set (i.e., plurality) of non-magnetic particles in the channel (page 31, lines 7-19). Thus, the sets of particles are arranged in a sequence.

Regarding claim 2, the system of claim 19 is discussed above. Burd Mehta et al also teach the system wherein the vessel holds first and second magnetic microparticles; namely, multiple sets of different particles are stacked (i.e., sandwiched) within the channel (page 29, lines 10-31), and that subsequent sets of particles are smaller magnetic particles (page 31, lines 7-19). Thus, the first layer of magnetic particles are the particle retention region of claim 1, which is followed by the layer of non-magnetic particles of claim 1, and the third layer is the set of smaller magnetic particles (page 31, lines 7-19). Burd Mehta further teach all of the types of particles are coupled (i.e., immobilized) to nucleic acids, and that particles serve many purposes

within the array vessels (page 4,lines 5-22), which is interpreted as every type of particle bearing an immobilized probe in the forum of a coupled nucleic acid.

Regarding claim 3, the system of claim 19 is discussed above. Burd Mehta et al further teach the system wherein at least one of the magnetic microparticles has a probe immobilized to a surface thereof; namely, Burd Mehta et al teach all of the types of particles, including magnetic particles, are coupled (i.e., immobilized) to nucleic acids (page 4, lines 5-22).

Regarding claim 4, the system of claim 2 is discussed above. Burd Mehta et al teach the system further comprises a detector and an analyzer in the form of a computer (Figure 12). Burd Mehta et al further teach the device comprising the computer detects and analyzes a bond between one of the probes and an organism related molecule included in the sample; namely, the device detects a specific nucleic acid (page 13, lines 1-15), which is an organism related molecule.

As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claim 4 (e.g., detecting a bond to an organism elated molecule) fail to define additional structural elements to the device. Because the prior art teaches the structural elements of claim 4, the claim is obvious over the prior art.

Regarding claim 6, the system of claim 19 is discussed above. Burd Mehta that teach the magnets create an electromagnetic field (page 20, lines 1-10), and that the magnetic members create a magnetic field proximal to the channel for magnetically controlling the position of the magnetic particles with respect to the vessel (page 22, line

29-page 23 line 10). Because Burd Mehta et al teach the magnetic field that is proximal to the channel is an alternative embodiment to a magnetic field within the particle retention region in the channel (page 23, lines 7-10), the magnetic control elements are interpreted as being outside the vessel.

In addition, Forrest et al teach a system in the form of conduit 56, which is a vessel, having a plurality of magnetic traps (i.e., members) 60 and 62 disposed outside the vessel (Figure 3a and column 9, lines 10-67).

Thus, modification of the system of Burd Mehta et al in accordance with the teachings of Forrest et al results in a plurality of electromagnets provided outside the vessel, which move the magnetic microparticles by controlling capturing to, and dissociation from, the electromagnets by varying the magnetic fields.

In addition, as noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claim 6 (e.g., capturing and dissociating particles) fail to define additional structural elements to the device. Because the prior art teaches the structural elements capable of performing the uses described in claim 6, and the claim is obvious over the prior art.

Regarding claim 7, the system of claim 19 is discussed above. Burd Mehta et al also teach the system wherein the vessel has branched channels; namely, Burd Mehta et al teach Figures 9A-B, which show channels 815-805 branching off of broad channel 915 (page 28, lines 1-9). Figures 9B also shows packets of mixed microparticles in each of the channels, wherein the packets are interpreted as the magnetic and non-magnetic microparticles.

As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claim 7 (e.g., taking particles out of a channel) fail to define additional structural elements to the device. Burd Mehta et al teach the particles are stored in an integrated external storage element and fluidically transferred to the channel region (page 89, lines 5-24), and that the plurality of magnetic members create a magnetic field proximal to the channel for magnetically controlling the position of the magnetic particles with respect to the vessel (page 22, line 29-page 23 line 10). Modification in accordance with the teachings of Forrest et al results in the magnets being switched on and off. Thus, the prior art teaches the structural elements of claim 7, and the claim is obvious over the prior art.

Regarding claim 8, the system of claim 19 is discussed above. Burd Mehta et al teach the system further comprises a combination of magnetic and electrophoretic transport systems within the microfluidic device (page 15, line 30-page 17, line 8). The magnetic and non-magnetic particles are therefore taken out of an opening end of vessel 415 of Figure 3A and transported through an electrophoresis channel (page 17, lines 1-29), which is the transport mechanism connected to the electrophoresis apparatus. Burd Mehta et al also teach a capillary sips a sample form a microtiter plate and delivers the sample to the channel (page 16, lines 8-10); thus, the elements are all connected.

In addition, as noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claim 8 (e.g., collecting the microparticles) fail to define additional structural elements to the device. Burd Mehta et

al teach the particles are stored in an integrated external storage element and fluidically transferred to the channel region (page 89, lines 5-24), and that the plurality of magnetic members create a magnetic field proximal to the channel for magnetically controlling the position of the magnetic particles with respect to the vessel (page 22, line 29-page 23 line 10). Modification in accordance with the teachings of Forrest et al results in the magnets being switched on and off. Thus, the prior art teaches the structural elements of claim 8, and the claim is obvious over the prior art.

Regarding claim 21, the system of claim 1 is discussed above. Burd Mehta et al teach the system further comprises a collecting vessel collecting one of the magnetic microparticles moved by the switching of the magnetic fields; namely, the arrays of particles are moved to a desired location within a microfluidic system (page 14, lines 5-11), wherein the system has a plurality of locations (Figure 8). Modification in accordance with the teachings of Forrest et al results in the magnets being switched on and off. Thus, the prior art teaches the structural elements of claim 21, and the claim is obvious over the prior art.

Regarding claims 23 and 29, and claims 26 and 32, the systems of claims 1 and 19 are discussed above. As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claims 29 and 23 (e.g., collecting non-magnetic and/or magnetic microparticles and one-by-one from an opening end of the vessel by on/off switching of the magnetic fields) and in claims 32 and 26 (e.g., collecting an individual one of the non-magnetic and/or magnetic microparticles from the vessel by the on-off switching of the magnetic fields) fails to

define additional structural elements of the claimed system. Because the prior art teaches the structural elements of the claims, the claims are obvious over the prior art.

Regarding claims 24 and 30, the systems of claims 1 and 19 are discussed above. Burd Mehta et al also teach the solution flow introducing means is arrange to introduce the solution so as to convey the particles one-by-one through the channel; namely, the beads are flowed into a channel to form a linear array wherein all of the beads (i.e., particle set 1610 of Figure 16) have the same mean diameter (page 26, lines 15-20)

Alternatively, Forrest et al also teach the solution flow introducing means is arranged to introduce the solution into the vessel so as to convey the magnetic particles from the opening end of the vessel; namely, the pump (i.e., solution flow introducing means) controls flow of the particles into the vessel (column 6, line 55-column 7, line 50). Thus, modification of the system of Burn Mehta et al with the teachings of Forrest et al results in a system wherein the solution flow introducing means is arranged to introduce the solution into the vessel so as to convey the particles one-by-one through the channel.

As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claims 32 and 24 (e.g., conveying the non-magnetic and/or magnetic microparticles one-by-one from an opening end of the vessel by on/off switching of the magnetic fields) fails to define additional structural elements of the claimed system. Because the prior art teaches the structural elements of the claims, the claims are obvious over the prior art.

Regarding claims 25 and 31, the systems of claims 1 and 19 are discussed above. Burn Mehta et al further teach a washing solution vessel arranged to hold a washing solution in the form of a reagent well, wherein the reagent is for washing and is controlled electrokinetically (i.e., by the solution flow introducing means; page 91, lines 20-30).

Alternatively, Forrest et al further teach the system comprises a washing solution vessel in the form of wash receptacle 18, which is connected to pump tube 12 (Figure 1 and column 6, line 55-column 7, line 50), and thus is connected to the pump (i.e., solution flow introducing means). Thus, modification of the system of Burn Mehta et al with the teachings of Forrest et al results in a system further comprising a washing solution vessel connected to the solution flow introducing means.

As noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claim 25 (e.g., introducing the washing fluid into the vessel before the magnetic members are set on) fails to define additional structural elements of the claimed system. Because the prior art teaches the structural elements of the claims, the claims are obvious over the prior art.

Regarding claims 27 and 33, the systems of claims 1 and 19 are discussed above. Burd Mehta et al also teach the vessel holds the particles in a single line; namely, the beads are flowed into a channel to form a linear array wherein all of the beads (i.e., particle set 1610 of Figure 16) have the same mean diameter (page 26, lines 15-20). Burd Mehta et al further teach each of the plurality of particles have a diameter that is larger than one half of the inner diameter of the vessel; namely, the

particles are larger than 12 microns and the diameter of the particle retention region is about 20 microns (page 24, lines 5-10).

Regarding claims 28 and 34, the systems of claims 1 and 19 are discussed above. Burd Mehta et al further teach "at least one member of the particle array is transported" on page 4, lines 20-30, wherein the "at least one member of the particle array" is interpreted as a single microparticle. Thus, because Burd Mehta et al teach transportation of a single particle of the array and that of the magnetic members create a magnetic field proximal to the channel for magnetically controlling the position of the magnetic particles with respect to the vessel (page 22, line 29-page 23 line 10), modification of the system of Burd Mehta et al with the teachings of Forrest et al results in a system wherein the switching on and off of the magnetic members results in the movement of single particles.

In addition, as noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claims 34 and 28 (e.g., conveying the non-magnetic and/or magnetic microparticles one-by-one from an opening end of the vessel by on/off switching of the magnetic fields) fails to define additional structural elements of the claimed system. Because the prior art teaches the structural elements of the claims, the claims are obvious over the prior art.

Response to Arguments

A. Applicant argues on pages 11-12 of the Remarks that because Burd Mehta et al allegedly teaches a retention element for trapping beads that is different

from the claimed setting on and off of the independently controlled magnetic members, no combination of Burd Mehta and Forrest et al reaches the invention of claim 1.

However, as noted above, Forrest et al teach magnetic members in the form of electromagnets (column 3, lines 35-45) that are operated in a particular timed sequence by a controller in the form of programmer 64 (Figure 1 and column 9, lines 10-67). The programmer independently sends signals to each of the magnetic members because the first magnetic tap is energized separately from the second magnetic trap (column 9, lines 34-65), and each of the magnetic members therefore are arranged to be set off by a corresponding one of the independently received signals and are downstream from the solution flow (Figures 3A-3C). Thus, the combination of Burd Mehta et al in view of Forrest et al teaches all of the structural limitations of the claimed invention.

B. Applicant argues on pages 12-13 of the Remarks that new dependent claims 23-34 are allowable due to their dependence on claim 1.

However, new claims 23-34 are rejected for the reasons presented above.

12. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burd Mehta et al (PCT International Application Publication No WO 00/50172, published 31 August 2000) in view of Forrest et al (U.S. Patent No. 4,141,687, issued 27 February 1979) as applied to claims 1 and 19 above, and further in view of Wang et al (U.S. Patent No. 5,795,470, issued 18 August 1998).

Regarding claim 5, the system of claims 1 and 19 is discussed above in Section 11.

Neither Burd Mehta et al nor Forrest et al explicitly teach the magnets are movably provided.

However, Wang et al teach a system comprising a vessel that is mounted in an array of magnets (Abstract and Figure 10), wherein the magnets are electromagnets (column 3, line 65-colum 4, line 5). Because the vessel is mounted in the array of magnets, the array of magnets are moved away from the vessel, and are therefore movably provided outside the vessel. Wang et al also teach the system has the added advantage of enhanced collection of biospecifically bound particles as a result of monolayering of particles within the vessel as controlled by the magnets (column 7, lines 25-65). Thus, Wang et al teach the known technique of having magnets that are movably provided.

It would therefore have been obvious to a person or ordinary skill in the art at the time the claimed invention was made to have modified the system as taught by Burd Mehta et al in view of Forrest et al so that the magnets are movably provided magnets as taught by Wang et al to arrive at the instantly claimed system with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in a system having the added advantage of enhanced collection of biospecifically bound particles as a result of monolayering of particles within the vessel as controlled by the magnets as explicitly taught by Wang et al (column 7, lines 25-65). In addition, it would have been obvious to the ordinary artisan that the known technique of using the movably provided magnets as taught by Wang et al could have been applied to the system of Burd Mehta et al in view

of Forrest et al with predictable results because the movably provided magnets as taught by Wang et al predictably results in a system useful in biomolecular assays.

Response to Arguments

Applicant' arguments on page 12 of the Remarks regarding the previous rejection of claim 5 rely on the alleged deficiencies of Burd Mehta et al in view of Forrest et al. These arguments are considered above. Because the arguments regarding the alleged deficiencies of Burd Mehta et al in view of Forrest et al were not persuasive for the reasons stated above, claim 5 remains rejected.

13. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burd Mehta et al (PCT International Application Publication No WO 00/50172, published 31 August 2000) in view of Forrest et al (U.S. Patent No. 4,141,687, issued 27 February 1979) as applied to claims 1 and 19 above, and further in view of Harrison et al (U.S. Patent No. 6,432,290 B1, issued 13 August 2002).

Regarding claim 9, the system of claims 1 and 19 is discussed above in Section 11.

While Burd Mehta et al also teach downstream detection is performed by mass spectrometry (page 55, lines 1-13), neither Burd Mehta et al nor Forrest et al explicitly teach the mass spectroscope is connected to the transport mechanism; i.e., fluidically integrated with the device.

However, Harrison et al teach a vessel comprising channels (Figure 10) and having a transport mechanism for collecting the microparticles from an opening end of

the vessel; namely, microparticles in the form of beads (Abstract) are fluidically pumped through an electrospray coupler to a mass spectrometer (Figure 10 and column 18, lines 7-25)) with the added advantage that an integrated system eliminated sample handling losses and contamination problems arising from off-device (i.e., off-chip) sample manipulation (column 4, lines 25-35). Thus, Harrison et al teach the known technique of fluidically integrating a mass spectroscope with a transport mechanism.

It would therefore have been obvious to a person or ordinary skill in the art at the time the claimed invention was made to have modified the system comprising transport of microparticles and mass spectrometry as taught by Burd Mehta et al in view of Forrest et al with the fluidic integration of the system and mass spectroscope as taught by Harrison et al to arrive at the instantly claimed system with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in a system having the added advantage of eliminating sample handling losses and contamination problems arising from off-device as explicitly taught by Harrison et al (column 4, lines 25-35). In addition, it would have been obvious to the ordinary artisan that the known technique of using the integrating a mass spectroscope as taught by Harrison et al could have been applied to the system of Burd Mehta et al in view of Forrest et al with predictable results because the integrated a mass spectroscope as taught by Harrison et al predictably results in a system useful in biomolecular assays.

Response to Arguments

Applicant' arguments on page 12 of the Remarks regarding the previous rejection of claim 9 rely on the alleged deficiencies of Burd Mehta et al in view of Forrest et al. These arguments are considered above. Because the arguments regarding the alleged deficiencies of Burd Mehta et al in view of Forrest et al were not persuasive for the reasons stated above, claim 9 remains rejected.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571)272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert T. Crow/
Examiner, Art Unit 1634

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